STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2050 (C04/2012)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
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EXISTING ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☐ Repeal ☒ Modification

2. Administrative Rule Chapter, Title and Number
Wis. Admin. Code ch. ATCP 77, Laboratory Certification

3. Date Rule promulgated and/or revised; Date of most recent Evaluation
2008

4. Plain Language Analysis of the Rule, its Impact on the Policy Problem that Justified its Creation and Changes in Technology, Economic Conditions or Other Factors Since Promulgation that alter the need for or effectiveness of the Rule.

The Wisconsin department of agriculture, trade and consumer protection ("Department") oversees the certification of 81 certified milk or food laboratories and the approval of 96 drug residue screening laboratories under a cooperative agreement with the food and drug administration (FDA) through the national conference on interstate milk shipments (NCIMS). The Department accredits 127 safe drinking water testing laboratories under a primacy agreement with the U.S. environmental protection agency (EPA) through the Wisconsin department of natural resources (WDNR).

Revised Fee Structure

The fees for laboratory certification were last updated in 2008. The proposed fee increases are 20% and consistent with the change in the consumer price index since 2008. The exception is the prorated monthly fee for the addition of a milk or water test to a laboratory's license mid-year. Those fees were not increased properly in 2008. Monthly fees now correctly reflect 1/12th of the annual fee.

• Annual fee for a laboratory, for each milk test they are certified for, changes from $410 to $492.

• Annual fee for a certified analyst changes from $30 to $36.

• Annual fee for a laboratory, for each water test they are certified for, changes from $340 to $408.

• The prorated fee for the addition of a test procedure mid-year changes from $23 to $35 per month for each water test, and from $28 to $42 per month for each milk test.

• The fee for a supplemental inspection done at a time other than the mandatory inspection changes from $150 to $180.

• Initial fee for licensing of a drug residue screening laboratory changes from $610 to $732 for most facilities, and from $150 to $180 for very small facilities.

• Drug residue screening laboratory annual fees change from $60 to $72 for most facilities, and from $30 to $36 for very small facilities.

Discretionary Inspection fees

ATCP 77 always referred to discretionary inspections, but the fees for this type of inspection were not clearly defined. The rule now specifies that the fee for a discretionary inspection is the same as the supplemental survey fee of $180.

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Documentation of temperature of temperature-controlled equipment

The rule required all laboratories to measure and record equipment temperatures at least daily. Many laboratories were thus required to bring in staff on a Sunday or holiday just to read and record equipment temperatures. Both the FDA and the EPA have allowed laboratories to not record the temperatures of equipment on days when the laboratory is not normally staffed. This change aligns ATCP 77 with the FDA and EPA and eliminates a staffing burden for laboratories.

Inspections every 3 years

Laboratories operating under the FDA cooperative agreement must be inspected once every 2 years. Laboratories operating under the EPA primacy agreement are only required to be evaluated once every three years. The Department's revised position is that those laboratories only doing water testing are only required to be evaluated once every three years. This change will allow laboratories and the department's program more flexibility in scheduling laboratory surveys.

Similar Methodology

The Department added language that states if a laboratory is certified for a specific test method and they want to add or switch to another test method that uses the same or very similar test methodology, the Department will not be required to inspect the lab. This change will speed up the certification process for laboratories looking to use a new test procedure. This will also save the laboratories money since they will not have to pay a supplemental survey fee.

Analyst term of certification and provisional status

As it is currently written in ATCP 77, analysts lose their certification if not present for a laboratory's mandatory inspection. The language will be changed to read that an analyst's certification is terminated when the laboratory administrator requests that the analyst's certification be withdrawn or the laboratory does not pay the analyst's annual renewal fee. Thus, if an analyst misses a laboratory's mandatory inspection, but the laboratory administrator does not request the withdrawal of that analyst, the analyst will be placed in provisional status.

Analysts in provisional status due to missing a mandatory inspection will remain in provisional status until they demonstrate their competence during an inspection of the laboratory, or they lose their certification because of a failure of proficiency testing or failure to be present for the laboratory's next mandatory inspection.

This change will put the rule in closer alignment with the FDA requirements and will create less of a hardship for analysts who miss an on-site evaluation due to family emergency or illness.

Fecal coliform to E. coli

The WDNR change in water testing, which targets bacteria from fecal coliform to E. coli for drinking water testing, required the Department to change the directions for preparation of the water proficiency samples to also contain the target organism of E. coli.

Other Revisions

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The rule contains other revisions to match updated terminology and technology, adds newly approved test procedures, and removes test procedures that are no longer approved or commercially available. Some revisions align the rule with recent changes in state and federal law. Among these revisions are the following:

• The Division name has changed from the Division of Food Safety to the Division of Food and Recreational Safety. This change has been made throughout the document.

• The rule expands the definition of milk to include the other species of animals (water buffalo and camelids) that are recognized by the FDA.

• The rule aligns the list of approved test procedures with the lists of currently approved procedures from the FDA and EPA, and corrects some of the technical names.

• The rule adds the requirement that the operator of a laboratory provide not just name and address, but also the e-mail address of the laboratory.

• The rule indicates current revisions of reference materials.

• As required, the new test procedures have been added to the proficiency evaluation standards specifying the number of samples that shall be run each year and how "acceptable" and "unacceptable" test results will be determined.

5. Describe the Rule's Enforcement Provisions and Mechanisms

The Department has specific authority under Wis. Stat. § 93.12 (5) to make and enforce regulations to establish uniform minimum standards to be used in the evaluation and certification of laboratory examinations. The Department also has authority under Wis. Stat. § 93.12 (7) to establish a fee schedule to offset the cost of certifying the laboratories and to regulate the collection of those fees. Additionally, the Department has general authority, under Wis. Stat. § 93.07 (1) to adopt rules to implement programs under its jurisdiction.

Division laboratory evaluation officers (LEO) visit laboratories to ensure they have the proper equipment and are capable of performing the proper procedures to produce accurate test results for the products being tested. These visits are conducted before the laboratory does any official testing and once every 2 years thereafter. If an LEO discovers a major violation during a routine visit that will compromise the laboratory's ability to produce accurate test results, the LEO can perform a chargeable re-survey.

Laboratories and analysts are also required to run proficiency samples. If a laboratory or analyst fails these proficiency samples, the laboratory or analyst will be placed in provisional status. If the laboratory or analyst fails a second time within a proscribed time frame, the laboratory or analyst license will be suspended for that specific test procedure.

6. Repealing or Modifying the Rule Will Impact the Following (Check All That Apply)

- ☐ State's Economy
- ☐ Local Government Units
- ☒ Specific Businesses/Sectors
- ☐ Public Utility Rate Payers
- ☒ Small Businesses

7. Summary of the Impacts, including Compliance Costs, identifying any Unnecessary Burdens the Rule places on the ability of Small Business to conduct their Affairs.

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The Department believes the changes proposed will have a minimal effect on small businesses. While fees are increasing, eliminating the need to conduct a supplemental survey if the lab switches to a similar test method, or an analyst misses a mandatory inspection, should help offset some of those costs. The overall cost of the fee increase over the entire program (both large and small businesses) is a total of approximately $35,864.

8. List of Small Businesses, Organizations and Members of the Public that commented on the Rule and its Enforcement and a Summary of their Comments.

Input and analysis was provided by Department experts, and the Department has reviewed statutory provisions and federal regulations. Further, the Department has gathered information over the last several years from stakeholders. The Department solicited information from industry about the potential economic impact of the rule, but no comments were submitted. A copy of the draft rule was presented at meetings to representatives of each type of laboratory affected by the proposed change, including the WDNR, the Wisconsin association of local health departments and boards, and the Wisconsin laboratory association.

9. Did the Agency consider any of the following Rule Modifications to reduce the Impact of the Rule on Small Businesses in lieu of repeal?

☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☒ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

10. Fund Sources Affected	11. Chapter 20, Stats. Appropriations Affected
☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG ☐ SEG-S	20.115 (1) (gb)

12. Fiscal Effect of Repealing or Modifying the Rule

☒ No Fiscal Effect	☐ Increase Existing Revenues	☐ Increase Costs
☐ Indeterminate	☐ Decrease Existing Revenues	☐ Could Absorb Within Agency's Budget
		☐ Decrease Cost

13. Summary of Costs and Benefits of Repealing or Modifying the Rule

Modernizing Requirements

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An analyst in provisional status due to missing a mandatory inspection will remain in provisional status until demonstrating competence during an inspection of the laboratory. Otherwise the analyst will lose certification because of a failure of proficiency testing or a failure to be present for the laboratory's next mandatory inspection.

This change will put the rule in closer alignment with the FDA requirements and will create less of a hardship for analysts who miss an on-site evaluation due to family emergency or illness.

Fecal coliform to E. coli

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• The rule expands the definition of milk to include the other species of animals (water buffalo and camelids) that are recognized by the FDA.

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• The rule adds the requirement that the operator of a laboratory provide not just name and address, but also e-mail address of the laboratory.

• The rule indicates current revisions of reference materials.

• As required, the new test procedures have been added to the proficiency evaluation standards specifying the number of samples that shall be run each year and how acceptable and unacceptable test results will be determined.

14. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☒ No

15. Long Range Implications of Repealing or Modifying the Rule

Adjusting ATCP 77 grants laboratories greater flexibility in day-to-day practices as well as an ease in staffing requirements. To begin with, analysts will no longer lose their certification if not present for a laboratory's mandatory inspection. Analysts will instead be put in provisional status until a competency demonstration is conducted, or they lose their certification because of a failure of proficiency testing, or failure to be present for the laboratory's next mandatory inspection. This change will put the rule in closer alignment with the FDA requirements and will create less of a hardship for analysts who miss an on-site evaluation due to family emergency or illness. The elimination of the requirement of off-day reading and recording of equipment temperatures aligns ATCP 77 with the FDA and EPA and will also eliminate a staffing burden for laboratories. The Department's change in position on the frequency of water laboratory evaluation to every 3 years will allow laboratories and the Department's program more flexibility in scheduling laboratory surveys. Laboratories looking to add or switch another test method will find ease in doing so with the addition of language that states that this no longer prompts an inspection. This change will speed up the certification process for laboratories looking to use a new test procedure. This will also save the laboratories money since they will not have to pay a supplemental survey fee.

16. Compare With Approaches Being Used by Federal Government

State milk and drug residue screening laboratories operate under a cooperative agreement with the FDA through the NCIMS. The laboratory certification program was established to be in accordance with the FDA documents, as well as the grade "A" pasteurized milk ordinance (PMO) and the evaluation of milk laboratories (EML), which are amended biennially. The latest revisions of these documents are dated 2017. The PMO is incorporated by reference in federal

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specifications for the procurement of milk and milk products and is used as the sanitary regulation for milk and milk products.

State water laboratories operate under a primacy agreement between the EPA and WDNR. The Department has a memorandum of understanding with the WDNR for the certification of these laboratories. The accreditation of water laboratories was established to be in accordance with the EPA's manual for the certification of laboratories analyzing water and wastewater. The Safe Drinking Water Act and the Revised Total Coliform Rule give the EPA the responsibility for ensuring the safety of drinking water in this country.

17. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Participation in the NCIMS requires a state milk regulatory program to meet the requirements laid out in the PMO and EML for approval of milk and milk products analysis laboratories. The water laboratory certification rules in Illinois are more proscriptive than Wisconsin. For example, the Illinois rule sets minimum requirements for use of specific pieces of equipment. The Wisconsin rule does not spell out this requirement, in turn, allowing greater flexibility to incorporate new technologies.

The Minnesota rule is more open in that it allows for mobile laboratories, but stricter in requiring laboratories to respond to any deficiencies found within 30 days. ATCP 77 does not proscribe a time frame which enables each program to determine its own time frames. The Minnesota rule also requires laboratories to have a written set of standard operating procedures, whereas ATCP 77 only requires reference materials to be kept on-site.

18. Contact Name	19. Contact Phone Number
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This document can be made available in alternate formats to individuals with disabilities upon request.